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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,437	03/02/2001	Thomas Charles Elleman	50179-086	9960

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EXAMINER
SHEINBERG, MONIKA B

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/701,437	ELLEMAN ET AL.
	Examiner	Art Unit
	Monika B Sheinberg	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 December 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-52 is/are pending in the application.
 - 4a) Of the above claim(s) 24-52 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-23 is/are rejected.
- 7) Claim(s) 5-23 is/are objected to.
- 8) Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 sheet.
- 4) Interview Summary (PTO-413) Paper No(s) _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-23, in Paper No. 7, filed 4 December 2001, is acknowledged. The traversal is on the ground(s) that the special technical feature linking the groups is the three dimensional structure of the EGF receptor. This is not found persuasive because each of the steps of methodology is different and distinct in groups I-III and VII, while each composition of groups IV-VI are patentably distinct. In addition, the composition of claim 36 can be isolated by other means, such as naturally, than by using the methods disclosed.

The requirement is still deemed proper and is therefore made FINAL.

Claims 24-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7, filed 4 December 2001.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-23 are rejected under 35 U.S.C. 101 because the method of the instant claims, the method of designing a compound consists solely of an abstract idea in which no concrete or tangible result is present. For example, claims 1-3 only describe, or characterize the molecule to which the compound of design is to bind to. Assessing the abilities or descriptive properties of the designed compound does not produce a concrete, tangible, and useful result. See MPEP § 2106:

Apart from the utility requirement of 35 U.S.C. 101, usefulness under the patent eligibility standard requires significant functionality to be present to satisfy the useful result aspect of the practical application requirement. See *Arrhythmia*, 958 F.2d at 1057, 22 USPQ2d at 1036. Merely claiming nonfunctional descriptive material stored in a computer-readable medium does not make the invention eligible for patenting. For example, a claim directed to a word processing file stored on a disk may satisfy the utility requirement of 35 U.S.C. 101 since the information stored may have some "real

“world” value. However, the mere fact that the claim may satisfy the utility requirement of 35 U.S.C. 101 does not mean that a useful result is achieved under the practical application requirement. The claimed invention as a whole must produce a “useful, concrete and tangible” result to have a practical application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-23 are indefinite for failing to recite a final process step which agrees back with the preamble. The basic steps of ligand or molecular design must be recited in a positive, active fashion. For example, claim 1 is drawn to a method for designing a compound that binds to a molecule, yet the claim recites only the characterization of the molecule to which the binding of the designed compound occurs. The description of the molecule continues in claims 2 and 3. Claims 4-23 continue only to describe that which occurs once the compound **is** designed. The critical steps of the actual design process are missing such that any design method could be utilized to have the final descriptive properties as recited in the claims. Claims recite such phrases as: “designed so as to complement the structure” (claim 4, line 2); and “compound has structural regions able to make close contact” (claim 5, line 2). Such limitations do not modify the method of claim 1. As such claims 1-23 are rendered vague and indefinite.

Claim 5 recites the limitation “the groove” in line 3. There is insufficient antecedent basis for this limitation in the claim. As such, claims 6-23 dependent from claim 5 are rendered indefinite.

Claims 8 and 11 recite the limitation “the hinge region” in line 2. There is insufficient antecedent basis for this limitation in the claim. As such, claims 15-23 dependent from claims 8 and 11 are rendered indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garrett et al (*Nature*, 1998) in view of Kuntz et al (*J. Mol. Biol.*, 1982) and Goodford (*J. Med. Chem.* 1985).

Garrett et al teaches the crystal structure of the EGF receptor which “contains the major specificity determinants for its ligands” (p.399, 1st column, 2nd paragraph), which appears to have the same structure set forth in claims 1-3. Figure 1 on page 396 clearly displays the recited L1 and L2 domain regions, including the β -sheets, as recited in claims 6-13. Although Garrett et al does not teach the use of the structure in molecular design as seen in claims 4-23, the reference motivates its use in ligand design by the suggestion that the “structure therefore shows how the [...] receptor...] might interact with their ligands” (p. 396, 1st column, 1st paragraph). Garrett et al clearly states that “a receptor can be constructed that binds [...] with comparable affinity” (p.397, 2nd column, 1st paragraph). One of ordinary skill in the art at the time of the invention would have been motivated to use the known structure of the EF receptor of Garret et al for ligand design by the study of ligand and receptor interaction such as taught by Kuntz et al.

Kuntz et al motivates the study of ligand and receptors of known structures for a method of designing of compounds by geometric alignments (abstract) that fit or complement the

structural matches. Kuntz et al motivates the use of the receptor in terms of having “grooves” (p. 161, 2nd paragraph, line 4) as recited in claim 5 that is depicted in the instant application’s figures 7, 8, and 9, in which the ligand is to fit into or interact with. Kuntz et al motivates the further modification of the method within the reference for refinement of ligand and receptor interactions by “us[ing] the structures generated [...] as a starting point for energy minimization” (p. 287, 2nd paragraph) as seen in the energy considerations of claims 15-16 and 21-23.

Goodford teaches the used of a known protein structure for molecular design by the selection of probes from a database with the most favorable energy levels, as recited in claims 15-17 and 21-23 (abstract). It is well known in the field of molecular design to utilize a molecules crystal structure for designing compounds in candidate drug design or ligand design which is motivated by Goodford on page 849 (1st column, 1st paragraph, lines 3-6): “[t]he novel molecules are designed so that they should fit onto an appropriate protein whose structure has been previously determined by X-ray crystallography”. Goodford clearly states the “fitting process is not just a matter of simple geometry [as seen in Kuntz et al] because the chemical properties of the individual atoms are critically important” (p. 849, 1st column, lines 6-8). The structure is used for studying compounds that effect, inhibit, or interfere with the target molecule’s activity as recited in claims 18-20.

It would have been *prima facia* obvious for one of ordinary skill in the art at the time the invention was made to have used the EGF receptor structure taught by Garrett et al for the design of binding ligands by methods disclosed by Kuntz et al. Kuntz et al disclose methods for the geometrical design of compounds to fit the ligand into a groove of the receptor. It would have further been obvious to have included the energy modeling features of the methods of Goodford, as Goodford et al. disclose the benefits of adjusting binding models for the most favorable energy levels. As the claims fail to set forth specific designing and modeling steps, and the specification indicates such steps were routinely performed at the time the invention was made, these methods of compound design by Kuntz et al for geometrical design and Goodford for energy considerations, in view of the crystal structure of the EGF receptor being known, clearly motivate the instant invention.

Claim Objections

Claims 5-23 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Conclusion

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (703) 306-0511. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.


MARY K. ZEMAN
PRIMARY EXAMINER


MARCH 5, 2002
Monika B. Sheinberg
Art Unit 1631